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10/598,315	04/08/2008	Lawrence Solomon	1322-035	2612

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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ipdocket@hgcpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,315	SOLOMON ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3,7-12 and 15-32* is/are pending in the application.

5a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,7-12 and 15-26* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 08/24/11 are acknowledged.

2. Claims 2, 4-6, 13-14, and 33 are cancelled. Claims 27-32 were withdrawn from consideration.

3. Claim 1 is amended.

4. Claims 1, 3, 7-12, and 15-26 are included in the prosecution.

Response to Arguments

Claim Objections

5. In light of the cancellation of claim 33, the objection regarding duplicate claims is withdrawn.

NEW REJECTION NECESSITATED BY AMENDMENT:

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 10 recites “A pharmaceutical tablet as defined in claim 1 in which said first segment is derived from a granulation that does not contain a drug.” However, claim 1, as amended, recites that the “first segment” is formed from the bottom active layer, i.e., the “first segment” contains an active ingredient according to claim 1. Therefore, it is

confusing how a "first segment" derived from an active layer that is broken can be derived from a granulation that does not contain a drug. Clarification is required.

For purposes of examination, the "first segment" as recited in claim 10 was interpreted as the "inactive segment" that is "derived from a granulation that does not contain a drug".

MAINTAINED REJECTIONS:

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

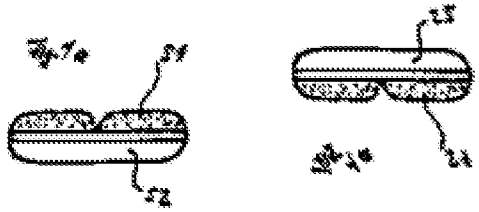
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims **1, 3, 7-9, 11-12, 15, and 17 remain** rejected under 35 U.S.C. 102(b) as being anticipated by Hess et al. (CH648754 – English Translation provided by Applicant).

The claimed invention is a compressed, layered pharmaceutical tablet comprising one or more layers forming a bottom active segment containing an effective amount of one or more drugs and a top inactive segment containing either an undetectable amount of drug or a pharmaceutically ineffective amount of drug, the inactive segment having a top and bottom face wherein only one of the faces contacts an active layer containing a drug or drugs, and the bottom active layer being scored by an embossed bottom punch to form substantially identical first and second unitary segments each having a top and bottom face wherein the top face of each unitary active

segment contacts the first inactive segment, wherein the terms “bottom” and “top” refer to the orientation of the tablet in the tablet die during compression.

Hess teaches a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided (Abstract, Fig. 1, and Example 1 - Page 4).



Regarding instant claims 1 and 15, the limitations of the tablet are anticipated by Figure 1 which shows a multi-layer (layer S1 and layer S2) tablet with a single break groove; wherein the active is present in one layer (S1) and there is a placebo (i.e., inactive) layer that does not contain a drug, as taught by Hess (Page 4). The terms “bottom” and “top” are relative to the orientation of the viewer of the tablet. If the tablet taught by Hess is rotated 180º, the same orientation as instantly claimed, i.e., bottom scored segment and top unscored segment, is achieved.

Regarding instant claim 3, the limitation of additional unitary segments in addition to the first and second unitary segments that are derived from the same layer or layers

as the first unitary segment is anticipated by Figure 3a which shows a tablet that may be divided into three parts, as taught by Hess.

Regarding instant claims 7-9, the limitations of the inactive layer are anticipated by the layer (S2) which does not contain a drug, as disclosed by Hess (Fig. 1 and Page 4).

Regarding instant claim 11, the limitation of the granulation containing a drug is anticipated by the active ingredient granulation taught by Hess (Page 4, Example 1).

Regarding instant claim 12, the limitation of the first and second unitary segments that are outer segments is anticipated by the outer segments taught by Hess (Figure 3a).

Regarding instant claims 17 and 33, the limitation of the drug that is effective in the treatment of cardiovascular conditions is anticipated by the metoprolol tartrate taught by Hess (Page 4, Example 1).

Response to Arguments

11. Applicant's arguments, see Page 8, filed 08/24/11, with respect to the rejection of claims 1, 3, 7-9, 11-12, 15, 17 and 33 under 35 U.S.C. 102(b) as being anticipated by Hess et al. (CH648754 –English Translation) have been fully considered but are not persuasive.

Applicant argues that because Hess does not teach a tablet having a bottom active layer which is scored, and a top inactive layer which is not scored, the cited reference cannot anticipate the claimed invention.

This is not persuasive because the terms "bottom" and "top" are relative to the orientation of the viewer of the tablet. If the tablet taught by Hess is rotated 180º, the same orientation as instantly claimed, i.e., bottom scored segment and top unscored segment, is achieved.

Therefore, the rejection of 05/24/11 is maintained.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims **10, 16 and 21-26 remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507).

Hess is discussed above.

Although Hess suggests a placebo layer being present (Page 4), this reference does not expressly teach a granulation that does not contain a drug.

Schmidt teaches a multi-layered tablet comprising one or more layers free from active substance and a layer containing an active substance (Abstract). Schmidt discloses advantages of the normal sized tablets that provide ease of handling and division (Col. 3, lines 11-24). Preparation of a multi-layer tablet is disclosed (Col. 3, lines 49-64 and Col. 4, lines 1-7). The example discloses that the placebo composition is prepared in the same way as the active granulation (Col. 4, lines 21-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to use a known technique (preparing a placebo or inactive layer composition in a multi-layer tablet by granulating the placebo composition – as taught by Schmidt) to

improve similar products (multi-layered tablet containing an active layer and a placebo or inactive layer – as taught by Hess). Please see MPEP 2141.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 10, the limitation of a granulation that does not contain a drug would have been obvious over the granulation of the placebo composition as taught by Schmidt (Col. 4, lines 21-54).

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the multilayered tablets, as taught by Hess (Abstract, Figures 1 and 3, and Page 4) in view of the multilayered tablets which may have one or more layers free from active substance, as taught by Schmidt (Abstract, Col. 3, lines 19-21 and Col. 4, lines 21-54). One of ordinary skill in the art would find it obvious to provide a plurality of layers or segments and manipulate these layers or segments based on the desired dosage form.

Regarding instant claims 21-22, the limitations of the first and second segments would have been obvious over the divisible tablet taught by Hess (Abstract, Fig. 1, Page 4) and by the multi-layered tablet taught by Schmidt (Abstract, Col. 3, lines 49-64 and Col. 4, lines 1-7 and lines 21-54). One of ordinary skill in the art would find it obvious to

arrange and manipulate the plurality of layers or segments during the process of routine experimentation based on the desired dosage form.

Regarding instant claims 23-26, the limitations of a method of breaking the pharmaceutical tablet and the method of administering a partial dose of a drug from the tablet would have been obvious over the divisible tablet taught by Hess (Abstract, Fig. 1, Page 4) and by the multi-layered tablet taught by Schmidt (Abstract, Col. 3, lines 49-64 and Col. 4, lines 1-7 and lines 21-54). One of ordinary skill in the art would find it obvious to break and divide the breakable tablets taught by Hess and Schmidt based on the desired dosage of drug to be administered since these are the advantages associated with divisible tablets (Hess – Abstract and Schmidt – Col. 3, lines 16-18).

Response to Arguments

14. Applicant's arguments, see Page 8, filed 08/24/11, with respect to the rejection of claims 10, 16 and 21-26 under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation) in view of Schmidt (US 4,786,507) have been fully considered but are not persuasive.

Applicant's clarification that at page 4 of the translated CH648754, Hess recites that "Figure 1 shows a tablet ... [wherein the active] layer can be S2, also as placebo layer present" and that this statement provides for a granulation that does not contain a drug is acknowledged. Applicant argues that the S2 layer is the bottom layer and is distinct from the subject invention, which claims the inactive granulation in the top layer.

This is not persuasive because, as discussed above, the terms "bottom" and "top" are relative to the orientation of the viewer of the tablet. If the tablet taught by Hess

is rotated 180º, the same orientation as instantly claimed, i.e., bottom scored segment and top unscored segment, is achieved.

Applicant argues that the bottom active layer must be scored in order to arrive at the tablet as claimed for the subject invention and a fully functional tablet of the subject invention is formed having a bottom active layer which is tamped prior to disposition of the top inactive layer. Applicant argues that: “A scored top layer requires that the embossing is on the top tablet punch. However, providing an embossed top punch precludes tamping because the tamping step, using an embossed top punch, will necessarily form an undesired indentation in the top face of the bottom layer.”

Applicant argues that Hess fails to describe tamping at all, which reinforces the applicants’ assertion regarding the failure of tamping the initial (bottom) layer and that this omission from the description in Hess is clearly due to the first layer of a tablet described by Hess being unable to be tamped using an embossed top punch.

This is not persuasive because the instant claims do not recite the limitation of tamping or any other product-by-process limitations that distinguish the instantly claimed tablet from the tablet disclosed by Hess. If a tamping step were claimed, arguendo, there is nothing precluding one of skill in the art from using a flat tamping punch, then filling the next layer and using an embossed punch to create the score. Thus, while examiner agrees that "using an embossed top punch, will necessarily form an undesired indentation in the top face of the bottom layer,” examiner does not agree that use of an embossed top punch would necessarily be used for the tamping step. One other point, assuming tamping is put into the claims, is that such method steps in a composition claim must be shown to result in a materially different product: “Once the

examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product." In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)

Applicant argues that the indentation formed by an embossed top punch is filled in by the second layer, resulting in incomplete separation of the scored active layer and a "bulged" interface between the active and inactive layers and this incomplete separation and bulged interface results in increased exposed surface area at the break plane, which can alter the release profile of a controlled release or matrix tablet, as compared to its profile as a whole tablet.

This is not persuasive because Hess teaches that "the slow release effect of the broken halves is only slightly changed from that of the whole slow release tablet" (Abstract).

Applicant argues that Hess describes and shows a tablet having a band around its perimeter, forming a flat side face, which is inconsistent with coating of the tablet as described by Hess because the flat face can result in adherence of those surfaces during the coating process, and "twinning" of the tablets when coatings are applied.

This is not persuasive because the instant claims do not exclude the band around the perimeter of the tablet. The coating and subsequent "twinning" due to the band around the tablet is not reported by Hess. The tablets are sprayed with a film-coating preparation, and successfully coated (Page 5).

Applicant argues that Schmidt does not cure the defects of Hess and that Schmidt is cited for its description of a placebo layer, an element that was erroneously stated in the Office Action to be absent from Hess.

This is not persuasive because Hess does not expressly teach a **placebo granulation** or a **granulation** that does not contain a drug. Hess suggests a placebo **layer** (Page 4) but does not teach the preparation or components of a placebo **granulation**. Schmidt was relied upon for teaching multi-layered tablets comprising one or more layers free from active substance wherein the placebo composition is prepared the same way as the active **granulation** (Col. 4, lines 21-54). This reference is properly combined with Hess because of the disclosure of advantages of the tablets in terms of ease in tablet division (Col. 3, lines 11-24). The limitations of a bottom active layer that is scored to provide unitary segments in the active layer, and a top inactive layer that is not scored, are taught by Hess.

Applicant argues that the Schmidt does not mention dividing the tablet through a score, nor does Schmidt describe the formation of unitary segments in the active layer to facilitate such division, as is expressly claimed for the subject invention. Applicant argues that Schmidt refers to a process diametrically opposed to the tabletting process steps forming the claimed tablets and that performing the procedure described in Schmidt would also necessarily omit scoring.

This is not persuasive because Schmidt is not relied upon for the formation of unitary segments. The primary reference, Hess, teaches and renders obvious the limitations of the bottom active layer that is scored and the top inactive layer that is not scored.

Therefore, the rejection of 05/24/11 is maintained.

Claim Rejections - 35 USC § 103

15. Claim **18 remains** rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Nesselroad, III (US 2004/0167207 A1).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug warfarin.

Nesselroad teaches that tablets of warfarin were halved along their scoring lines in order to create smaller dosage steps between doses of warfarin and for easy daily dosing (Page 5, [0043]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, in view of the use of warfarin as an active drug in a multi-scored pharmaceutical tablet, as taught by Nesselroad, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because divisible tablets with warfarin (tablets with scoring lines) were known in the art, as evidenced by the teaching of Nesselroad. Moreover, Nesselroad teaches the desirability of creating smaller dosage steps between doses of warfarin since “at the lower warfarin

doses, the interval between easily taken amounts is a significant dose change" (Page 5, [0043]).

Regarding instant claim 18, the limitation of warfarin would have been obvious over the tablets of warfarin that were halved along their scoring lines as taught by Nesselroad (Page 5, [0043]).

Response to Arguments

16. Applicant's arguments, see Page 11, filed 08/24/11, with respect to the rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation) in view of Schmidt (US 4,786,507) and further in view of Nesselroad, III (US 2004/0167207 A1) have been fully considered but are not persuasive.

Applicant argues that the reference Nesselroad further fails to cure the deficiencies of Hess and Schmidt taken alone or together. This is not persuasive because, as discussed above, Hess teaches and renders obvious the limitations of the bottom active layer that is scored and the top inactive layer that is not scored. The deficiency in Hess regarding the "granulation that does not contain a drug" is remedied by Schmidt. Hess and Schmidt do not expressly teach the drug warfarin. This deficiency is remedied by Nesselroad. The references are properly combined because divisible tablets with warfarin (tablets with scoring lines) were known in the art, as evidenced by the teaching of Nesselroad. Moreover, Nesselroad teaches the desirability of creating smaller dosage steps between doses of warfarin since "at the lower warfarin doses, the interval between easily taken amounts is a significant dose change" (Page 5, [0043]).

Therefore, the rejection of 05/24/11 is maintained.

Claim Rejections - 35 USC § 103

17. Claim **19 remains** rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Eberlin et al. (US 3,696,091).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug digoxin.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, in view of the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to combine prior art elements according to known methods (incorporating digoxin in a tablet and preparing a multilayered, divisible tablet) to yield predictable results. Please see MPEP 2141.

Regarding instant claim 19, the limitation of digoxin would have been obvious over the tablet of digoxin as taught by Eberlin (Col. 12, lines 20-45).

18. Claim **20 remains** rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Franz et al. (US 6,555,581 B1).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug levothroxine.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, further combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to combine prior art elements according to known methods (incorporating levothyroxine in a tablet and preparing a multilayered, divisible tablet) to yield predictable results. Please see MPEP 2141.

Regarding instant claim 20, the limitation of levothroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

Response to Declaration

19. The Declaration filed under 37 CFR 1.132 by Dr. David P. Beach on 08/24/11 has been fully considered but is not persuasive.

The declarant argues that "the tablets of the invention are expressly claimed as having a score on the bottom (active) segment or layer only, and having the inactive layer as the top layer. By contrast, Hess does not describe a tablet without a score on the top layer and provides only that the bottom layer is an inactive composition." The declarant argues that "the tablets of the invention require a uniform or level surface for each layer which is achieved by tamping the first layer - a score on the top surface of the tablet, as described by Hess, precludes tamping of the first layer."

This is not persuasive because the terms "bottom" and "top" are relative to the orientation of the viewer of the tablet. If the tablet taught by Hess is rotated 180º, the same orientation as instantly claimed, i.e., bottom scored segment and top unscored segment, is achieved. The instant claims do not recite the limitation of tamping or any other product-by-process limitations that distinguish the instantly claimed tablet from the tablet disclosed by Hess.

The declarant argues that "a tablet as described in the Hess reference is inoperable and cannot provide the features or advantages provided by the tablets of the invention" and that "without tamping of the first granulate with the upper punch to

provide a uniform and level surface, it is impossible to provide a functional tablet because compression of the active layer to a placebo or another active layer results in extrusion of the first active INTO the placebo or second active layer." The declarant argues that "given that only a maximum of 40-50% of the tablet contains the described score, breakage of the tablet along the score would result in the production of a new surface for diffusion from the matrix, and therefore an increase in the rate of release from the broken segments. When coupled with the already described dosing issues … based on the disclosed tooling design, these two factors would combine to produce an unacceptable final product from both a dosing and release rate perspective."

This is not persuasive because the orientation of the top and bottom layers of the tablet disclosed by Hess is relative and the reference does not disclose any problems with preparing the tablet, coating it or dividing it. In fact, Hess states that "the slow release of the broken halves is only slightly changed from that of the whole slow release tablet" (Abstract). The figures in the Hess reference do not show the extrusion of the active layer into the placebo/inactive layer. Furthermore, the instant claims do not recite any tooling design limitations.

The declarant argues that "Hess further describes and depicts a tablet that includes a "band" around its perimeter wherein the face of the band is flat. Therefore any type of tablet coating operation … following compression will result in these flat surfaces adhering to one another resulting in "twins" which would produce an unacceptable final product."

This is not persuasive because instant claims do not exclude the band around the perimeter of the tablet. The coating and subsequent "twinning" due to the band

around the tablet is not reported by Hess. The tablets are sprayed with a film-coating preparation, and successfully coated (Page 5).

Therefore, the rejections of 05/24/11 are maintained.

Conclusion

20. No claims are allowed.

21. Since the new rejection under 35 USC § 112, second paragraph, was necessitated by applicant's amendment, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

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